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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/477,371	01/06/2000	MING-TANG CHANG	2461-60	9152

7590 10/22/2002
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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 10/22/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/477,371

Applicant(s)

CHANG ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,14,17,18,21 and 23-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1,2,14,17,18,21 and 23-30 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The Amendment filed August 7, 2002, paper no.12, has been entered.

Claims 3-13, 15-16, 19-20 and 22 are cancelled.

Claims 2, 14, 17, 18, 21, and 23 are newly amended.

Claims 24-30 are newly added.

Claims 1-2, 14, 17-18, 21, and 23-30 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed June 20, 2002, Paper No. 10, is attached to the instant Office action.

Specification

The objection to the specification for not containing an abstract of the disclosure as required by 37 CFR 1.72(b) is withdrawn in light of the submission of an abstract on a separate sheet.

The objection to the specification for omitting an Accession No. on page 8 line 16 is withdrawn in light of the amendment of the specification.

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The specification remains objected to because data is omitted from the table spanning pages 37-38, and because the units of measure are not specified for the data in the table spanning pages 37-38, for the reasons of record set forth in the office action mailed February 7, 2002.

Applicant's arguments filed August 7, 2002, have been fully considered but they are not persuasive.

Applicant argues that the Table spanning pages 37-38 is not believed to require further amendment, and that more specifically, the amounts of protein and oil indicated in the table will be understood to refer to weight percent protein and oil, as recognized by one skilled in the art and referred to throughout the specification and claims (reply pages 5-6).

The objection is maintained, as amounts of protein and oil may be expressed in a variety of different ways.

Claim Objections

The objection to claim 21 as being a substantial duplicate of claim 23 is withdrawn in light of the amendment of claims 21 and 23.

Claim Rejections - 35 USC § 112

Claims 1-2, 14, 17-18, 21 and 23 remain rejected, and newly added claims 24-30 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed February 7, 2002.

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Applicant's arguments filed August 7, 2002, have been fully considered but they are not persuasive.

Applicant argue that access to the deposited materials should not be required to make and use the claimed invention, as applicants have readily described an embodiment of the claimed invention wherein mutagenesis is used along with selection. Applicants argue that mutagenesis is well known to those of ordinary skill in the art, and that methods of testing mutagenized materials are also well known (reply pages 6-7).

The Office maintains that access to the deposited materials should be required to make and use the claimed invention, as the seed claimed is essential to the claimed invention and must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The method of mutagenesis and selection set forth in the specification is not a repeatable process to obtain the exact same seed in each occurrence, and the seed claimed is not otherwise readily available to the public.

Claims 1-2, 14, 17-18, 21 and 23 remain rejected, and newly added claims 24-30 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the mutant corn seed designated UO95py, does not reasonably provide enablement for other mutant corn seed, or mutant seed of other cereal plant species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed February 7, 2002.

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Applicant's arguments filed August 7, 2002, have been fully considered but they are not persuasive.

Applicant points out that a variety of methods of mutagenesis are well known in the art, and that a disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used to describe and define the subject matter must be taken in compliance with the requirements of 35 USC 112, first paragraph, unless there is reason to doubt the objective truth of the statements which must be relied upon for enabling support. Applicant argues that the Examiner has failed to indicate why one skilled the art would have reason to doubt the objective truth of the statements which must be relied upon for enabling support (reply page 7). In response to the Examiner's assertion that the disclosure does not provide any example of non-lethal mutant cereal seed having at least 5% by weight oil, at least 11% by weight protein, and at least one-third reduction in phytic acid, Applicant points to page 38 and the exemplified mutant UO95py which contains 14.4 weight percent protein, 5.3 weight percent oil, and 85.3% phytate reduction (reply pages 7-8). With respect to the Examiner's comments regarding the unpredictability of altering the phenotype of seed by known mutagenesis techniques, Applicant points out that the claimed phenotypes are produced by mutagenesis as part of a population which may be selected for their advantageous properties. Applicant argues that undue experimentation would not be required to practice the claimed invention, and that absolute predictability is not required (reply page 8).

As stated in the office action mailed February 7, 2002 at pages 4-5, EMS mutagenesis is nonspecific, the identity and number of genes altered by EMS treatment cannot be controlled or predicted, and the effect of EMS mutagenesis on the oil, protein, and phytic acid content of

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mutant seed also cannot be controlled or predicted. The Office maintains that this unpredictability is indicative of why one skilled in the art would have reason to doubt the objective truth of the statements which must be relied upon for enabling support. While absolute predictability is not required, the experimentation required to practice the claimed invention must not be undue. In the instant case, undue experimentation would be required to practice the claimed invention. The specification does not provide sufficient guidance for one skilled in the art to determine how to employ EMS mutagenesis in order to reliably obtain the desired phenotype, or how to determine which EMS mutagenized seed to select for screening in order to be likely to identify the desired phenotype. Additionally, while the Office accepts Applicant's assertion that the mutant UO95py contains 14.4 weight percent protein, 5.3 weight percent oil, and 85.3% phytate reduction, thus meeting the limitations of a non-lethal mutant cereal seed having at least 5% by weight oil, at least 11% by weight protein, and at least one-third reduction in phytic acid, the Office maintains that this assertion is not explicitly exemplified in the specification at page 38, because the units of measure are not specified for the data in the table at page 38. Furthermore, the exemplification of a single seed line that meets the limitations of a non-lethal mutant cereal seed having at least 5% by weight oil, at least 11% by weight protein, and at least one-third reduction in phytic acid does not provide sufficient guidance for one skilled in the art to identify other seed lines that meet these limitations.

The rejection of claims 2, 14, 17-18, 21 and 23 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the indefinite article "A" before "seed", is withdrawn in light of the amendment of claims 2, 14, 17-18, 21 and 23.

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The rejection of claims 21 and 23 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of are indefinite in the recitation of " at least 9% protein", is withdrawn in light of the amendment of claims 21 and 23.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
October 18, 2002

 10/21/02
PHUONG T. BUI
PRIMARY EXAMINER